IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
TRENTON VICINAGE
HONORABLE FREDA L. WOLFSON

LAWRENCE SELINGER and EMILIA SELINGER, HIS SPOUSE, Plaintiffs, vs. ZIMMER INC, ABC CORPORATIONS (1-10), JOHN DOE and MARY ROE (1-10), fictitious names, persons intended being of unknown names, Defendants.	Civil Action No. 3:07-cv-05650 Honorable Freda L. Wolfson, U.S.D.J. Honorable Douglas E. Arpert, U.S.M.J

JOINT FINAL PRETRIAL ORDER

The following shall constitute the Final Pretrial Order pursuant to Rule 16, Federal Rules of Civil Procedure. This Final Pretrial Order shall govern the conduct of the trial of this case. Amendments to this Order will be allowed only in exceptional circumstances to prevent manifest injustice. *See* Fed. R. Civ. P. 16(e). Counsel are urged to move to amend in a timely fashion any portion of the Order that must be changed or modified between the filing of the Order and the trial date.

1. JURISDICTION

Jurisdiction is pursuant to 42 U.S.C. § 1332 based upon diversity of citizenship and an amount in controversy which exceeds the sum or value of Seventy-five Thousand Dollars ($75,000), exclusive of interest and costs. Plaintiffs are residents of New Jersey and defendant Zimmer is a Delaware corporation which operates from principal places of business located in Indiana.

2. PENDING/CONTEMPLATED MOTIONS

A. Plaintiffs have none.

B. Defendant has filed a Motion for Summary Judgment (Record Document "R.D." 19) and a Motion *in Limine* to exclude Testimony of Plaintiffs' Expert, Alfred J. Tria, Jr., M.D.(R.D. 20). Defendant also intends to file motions *in limine* to exclude from evidence certain proposed testimony and exhibits offered by Plaintiffs, including testimony and exhibits set forth in Sections 6, 8, 9 and 11 below, which are inadmissible under the Federal Rules of Evidence.

3. STIPULATION OF FACTS

1. Lawrence Selinger was born on August 12, 1934.

2. He is currently 75 years old and enjoying an active retirement – he plays golf four times a week, and also frequently sails, bikes, swims and occasionally joins his wife in Pilates exercises.

3. Before his total knee replacement, Dr. Selinger had a long history of knee pain. He had right knee arthroscopic surgery performed in 2002.

4. In 2003, Dr. Selinger began suffering from increased knee pain and was eventually diagnosed with degenerative joint disease in February, 2004, by Frank Cook, M.D. Dr. Cook presented Dr. Selinger with a number of surgical and non-surgical treatment options. Ultimately, he recommended oral anti-inflammatory medication and a modification of activities as Dr. Selinger's symptoms allowed.

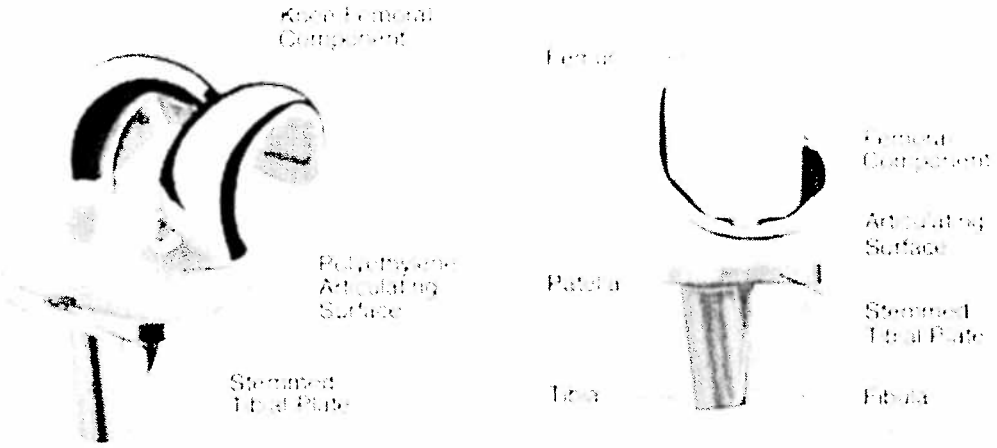
5. Dr. Selinger, an oral surgeon, engaged in extensive research regarding knee replacement surgical techniques and the surgeons who practice these techniques. In May 2004, Dr. Selinger sought a second opinion from Dr. Tria after hearing a radio program in which Dr. Tria discussed his success implanting Zimmer knee products.

6. At his consultation with Dr. Tria, Dr. Selinger complained of pain after 18 holes of golf or after walking for half an hour to an hour. Dr. Tria suggested that he stay on a conservative, non-surgical protocol.

7. In July 2004, however, Dr. Selinger complained of increased knee pain and decreased function and elected to undergo a right total knee replacement.

8. On August 9, 2004, at Saint Peter's University Hospital, Alfred Tria, MD, performed a total knee replacement upon plaintiff, Lawrence Selinger using the NexGen Complete Knee Solution System ("NexGen Knee"), designed, manufactured, sold and distributed by defendant Zimmer, Inc.

9. The NexGen Knee consists of a metal femoral component, a tibial base plate that covers the tibia, a polyethylene tibial articular surface that snaps into the tibial base plate, and a dome-shaped patellar component.



10. Specifically, plaintiff's implant was composed of the following components:

a. Stemmed Tibial Component, Size 7, Product Code 5980-57-01 Lot 60148240 ("tibial component");

b. Femoral Component, Product Code *5964-15-02*, Lot 60141745;

c. LPS-Flex Polyethylene Tibial Articular Surface Size E F 10mm height, Product Code 5960-51-10, Lot 60005138 ("tibial or polytehtylene insert"); and

d. All Ploy Patella Standard size 32mm dia. 8.5mm thickness, Product Code 5972-65-32, Lot 60166060.

11. The NexGen Knee is a prescription medical device, selected and prescribed by a physician.

12. Each package of the product contains an information sheet, called a "package insert," that provides to physicians information on the product, including the risks associated with its use. The package insert warns that the NexGen Knee, like other orthopaedic prostheses, may fail due to loosening.

13. Dr. Selinger initially recovered well from the knee replacement surgery. He was playing golf within 6 weeks of the surgery. By May 5, 2005, he reported having no pain in his knee.

14. In August 2006, however, Dr. Selinger began complaining of right knee pain. He voiced concern with his decreased ability to enjoy a number of activities, including golfing and biking. On September 13, 2006, Dr. Tria performed Dr. Selinger's revision surgery at St. Peter's University Hospital.

15. Plaintiffs are alleging a manufacturing defect regarding the NexGen Knee.

16. Specifically, Plaintiffs allege that the tibial component and tibial insert had a manufacturing defect, which caused backside wear of the polyethylene insert.

4. PLAINTIFFS' CONTESTED FACTS

Plaintiffs intend to prove the following contested facts with regard to liability:

1. Dr. Tria concluded, based upon Dr. Selinger's symptom complex and physical examination that he was a candidate for a total knee replacement.

2. Dr. Selinger's post-operative course initially was benign, but within several months, Dr. Selinger developed weakening of his leg and knee pain and swelling, which became progressively worse over time.

3. The deterioration of Dr. Selinger's right knee led to Dr. Selinger returning to Dr. Tria's care in August, 2006.

4. Physical examination showed mild effusion. X-rays showed some loss of bone underneath the tibial tray. A bone scan showed loosening of the tibial component. On September 13, 2006, Dr. Tria explanted the NexGen knee, and replaced it with another prosthesis.

5. At surgery, Dr. Tria found that all components of the artificial knee were loose. Dr. Tria also observed at surgery that the backside or posterior surface of the polyethylene insert was worn with loss of lettering, a condition called backside wear.

6. The backside wear of the polyethylene insert was caused by a manufacturing defect, the failure of the locking mechanism and the fit between the insert and the tibial tray.

Plaintiff intends to prove the following contested facts with regard to damages: (This must include each item of damages, the amount of each item, the factual basis for each item and,

if punitive damages are claimed, the facts upon which plaintiff rely to establish punitive damages).

1. As a result of the manufacturing defect, which led to the need for Dr. Tria to explant the NexGen, plaintiff experienced pain, limitations of motion and disability. His activities became limited and he had to undergo revision surgery and suffer the pain and disability associated with that surgery. He has residual complaints of pain and limitations of motion and will suffer in the future and has permanent problems.

2. Plaintiff also suffered economic loss, which he summarizes as follows:

Dr. Alfred Tria	4,037.31
Dr. Thomas Dean	1,000.00
Dr. Chris Kawa	1,080.00
Dr. Richard Medina	237.11
Dr. Marvin Seltzer	850.00
Dr. Paul Hiley	56.85
St. Peters Hospital	57,332.77
St. Peters Hospital	39,751.12
JFKennedy Rehab	16,498.43
Dr. Lin Lee Medical Care @ JFK	1,033
Community Medical Center	1,062
Ocean County Medical Lab	262.50
Kimball Medical Center	198.59
Robert Wood Johnson	245.20
Eric Roberts PT	1,125
All Care Rental - CMP Machine	253
Human Touch	930
Joe Nicastro	285
Mark Ortman PT	2,400
Advantage Physiotherapy	2,429
Advantage Physiotherapy	1,811.31
Upledger Institute	875
Flexage Stretch Massage	90
Anesthesia Associates	1,980
University Radiology Group	51.36
Health & Rehab Center 2006	2,400
Health & Rehab Center 2007	3,250
Body & Soul Therapy- 2005	135
Body & Soul Therapy- 2006	140
Body & Soul Therapy- 2007	340
Roseanna Ellis, PT - 2007	120
Human Touch Massage Therapy	930
Louisa Martinez Massage Therapy	1,275
Spine Therapy	1,125
Prescription Drugs	250
Dr. Robert Diaz	255
Dr. Robert Diaz	306
Shore Rehabilitation	10,105
Mark Ortman PT	1,200

Roseanna Ellis - 5/2007	240
Roseanna Ellis -	1,300
Well Again PT	1,280
Well Again PT	1,430
Well Again PT	200
Four pairs of knee stockings	259.16
Ambulance transportation 9/16/07	178.00
Transportation from JFK to Rehab	115.00
Round trip Taxi service to physiotherapy	140.00
Chi Pain Relieving machine	1,064.00
The above represents total charges but Dr. Selinger's personal out of pocket expenses were:	$16,450.16
Cancellation of Non-refundable pre-paid events; loss of use of gym, golf, etc.	$56,140.00

5. DEFENDANT'S CONTESTED FACTS

1. The NexGen Knee has a long and successful clinical history. Dr. Tria has testified that he has used this device over a thousand times with good clinical results. He implanted hundreds before Dr. Selinger's surgery and has implanted hundreds since.

2. Wear and loosening are known and inherent risks of knee replacement due to the biomechanics of the knee and knee arthroplasty.

3. The cause of loosening is variable and dependent on multiple factors, including (1) patient factors such as weight, height and other anatomic variables, as well as activity level, patient gait, and other loading scenarios; and (2) surgical factors such as the cementing technique and the application of bone cement, mechanical alignment of the limb, the relative positions of the components, selection of the appropriate product and the appropriate size, removing an appropriate amount of bone, and other variables of the implanting surgeon. The contributions of these factors must all be considered when assessing a clinical outcome and a mechanism of failure of an arthroplasty. Not only is each of these variables clinically significant individually some or all of them work in combination with others. The result is a range of factors impacting the clinical outcome of a total knee arthroplasty.

4. Loosening is one of the most frequent reasons for knee revision in the United States.

5. The knee joint is one of the most mobile and heavily loaded joints in the body. The load to a healthy knee joint is transmitted from the femur, through the menisci, and into the tibia. The load transmission pathway for a person with a total knee replacement, however, is altered. When the joint load passes through a cemented prosthesis, it must then pass through the bone cement. The bone cement acts as a filler material or grout between the prosthesis and the inside of the bone.

6. When the load passes through the bone cement, there are two interfaces that must carry the load: the implant-cement interface, and the cement-bone interface. A cemented prosthesis may loosen at the implant-cement interface, the cement-bone interface, or both. Mechanical loosening at the implant-cement interface occurs when the stresses applied to the fixation interface exceeds the bond strength of that interface.

7. This initial interface strength is variable and dependent on several factors. When a cemented component is well-fixed, the cement is intimately opposed to the adjacent implant and no space is seen between the implant and cement on clinical x-rays.

8. When the fixation between the cement and the implant is disrupted, the space between the two surfaces can be seen on radiographs and is referred to as radiolucency. Fixation is a continuum and in general, the more extensive the radiolucency, the greater the compromise of fixation.

9. The surface of polyethylene inserts may also become damaged *in vivo* from fragments of bone and bone cement. Bone cement particles are residual from the original cement fixation of the metal components in the joint, whereas bone particles can result from the cutting procedures during installation of the prosthesis. Bone as well as bone cement may cause "third body" wear of the UHMWPE by indenting the plastic surface and by scratching the metal surface.

10. Wear typically occurs when the UHMWPE tibial and patellar components articulate against the femoral component during a patient's normal daily activities.

11. The stress imparted on the UHMWPE component is related to the design of the implant, the material properties, and the joint loading. For tibial components, the joint forces are high, and expressed in terms of the patient's body weight. For walking, squatting, rising from a chair, or stair climbing/descent, the forces across the tibiofemoral joint can range from 3 to 7 times body weight.

12. Polyethylene wear can occur independent of any product defect, and like mechanical loosening, is multifactorial. Factors that cause wear include patient

factors like weight and patient activity level, and surgical factors including malalignment and surgical technique.

13. No artificial knee implant has solved the problem of wear.

14. Dr. Kurtz, a biomechanical engineer and expert on the use of ultra-high molecular weight polyethylene ("UHMWPE") in total joint replacements, opined that the Device contained no manufacturing or design defect, but rather found evidence consistent with cement debris damage. In support of his opinions, Dr. Kurtz found that fragmented bone cement had been embedded in the surface of the articular surface and had caused pitting. This embedded bone cement had also resulted in scratching of the femoral component. He found that the damage caused by this bone cement to the articular surface was much greater than the minor backside wear damage that is typical of use and opined that backside wear was not the reason for the revision of Dr. Selinger's knee.

15. Dr. Clark, an orthopedic surgeon, also opined that the Device contained no manufacturing or design defect, but rather found evidence consistent with cement debris damage. Dr. Clark further stated that the revision surgery was not the result of any deficiency or defect in the design or manufacturing of the NexGen Knee implanted in Dr. Selinger. Dr. Clark explained that loosening is frequently multifactorial and dependent upon factors including: (1) patient factors such as weight, height, and other anatomic variables, as well as activity level, patient gait, and other loading scenarios; (2) surgical factors such as the cementing technique and the application of bone cement, mechanical alignment of the limb, the relative positions of the components, selection of the appropriate product and the appropriate size, removing an appropriate amount of bone, and other variables of the implanting surgeon; and (3) the Device. In this case, Dr. Clark observed backside wear that is typical of explanted components, and not to a degree of clinical significance.

16. Zimmer developed the design and methods of manufacturing the NexGen Knee according to the best available state-of-the-art technology.

17. For every NexGen Knee manufactured, Zimmer maintains manufacturing records that document the manufacturing and inspection process for a particular device. The manufacturing records for the Device implanted in Dr. Selinger reflect no design or manufacturing deviations and that the Device met specifications in all respects.

18. There was no defect in manufacturing this NexGen Knee or in any of its components.

19. The primary damage mechanism in Dr. Selinger's tibial insert was scratching and pitting of the primary articulating surface, which was attributed to third body debris, including bone cement.

20. The fragmented bone cement contributed to wear and damage of the UHMWPE in two ways. By embedding in the surface, it caused pitting. However, the embedded debris also resulted in scratching of the femoral component. The damage caused to the articulating surface is much greater in severity than the backside wear damage.

21. Measurements of the magnitude of backside wear indicate that the amount of wear was within normal parameters. Contrast enhanced micrograph of the backside lateral condyle shows the engraved identification number was clearly visible leading to the conclusion that backside wear is less than 50 micrometers on the lateral backside. Because the back surface of the medial condyle is subjected to 50% greater forces, Dr. Kurtz concluded that backside wear is less than 75 micrometers on the medial backside. These conclusions are supported by the results of microCT analysis, which show the backside wear features to an order of magnitude less than those on the articulating surface.

22. Intraoperative photographs taken at Dr. Selinger's revision surgery clearly demonstrate that an intact bone cement mantle underlying the tibial insert. The intact bone cement mantle conclusively supports that failure the failure occurred at the implant-***cement*** interface of the tibial component, rather than at the cement-bone interface. If the loosening was aseptic and the result of osteolysis, the failure would have occurred at the cement-***bone*** interface.

23. Mechanical failure of the cement-implant interface is consistent with observations of bone cement third body wear debris embedded in the articulating surface of the polyethylene component. Dr. Tria, without further examination beyond the operating room or conducting any tests on the Device, opines that the Device exhibited "backside wear" and that this was the cause of the loosening.

24. Dr. Selinger's damage calculations are not supported by the record and applicable case law. Many of Plaintiffs out of pocket expensive may have been paid or reimbursed by other sources.

6. **PLAINTIFFS' WITNESSES**

A. On liability, plaintiffs intend to call the following witnesses who will testify in accordance with the following summaries:

1. Dr. Lawrence Selinger
4 Twilight Drive
Brick, NJ 08723

Dr. Selinger will describe his injuries based on his medical history, his knee problems that led to original implant post operative course, the development of problems following the original implant, the circumstances surrounding the revision surgery and his post operative course.

2. Dr. Alfred J. Tria, Jr., M.D.
Orthopaedic Center of New Jersey
1527 State Highway 27 - Suite 1300
Somerset, New Jersey 08873

Dr. Tria will testify about his qualifications and background with respect to knee replacements, his familiarity with the product at issue here, the care and treatment he provided to Dr. Selinger and his observations and conclusions concerning the original prosthesis and its manufacturing defect.

B. On damages plaintiffs intend to call the following witnesses who will testify in accordance with the following summaries:

1. Dr. Selinger will describe the pain, suffering, disability and economic loss associated with the failure or the original prosthesis.

2. Mrs. Selinger will describe her observations of the pain, suffering and disability associated with her husband's need for revision surgery.

3. Dr. Tria will testify will testify about his care, treatment and prognosis with respect to Dr. Selinger's knee.

C. Defendant objects to the following witnesses for the reasons stated:

Dr. Tria has no qualifications to opine in the following areas:

(a) Alleged Manufacturing defect
(b) Causation
(c) Bio-mechanical Engineering

See Zimmer Inc.'s Brief in Support of Its Motion *In Limine* to Exclude the Testimony of Plaintiffs' Expert Alfred J. Tria, Jr., M.D., Record Document 20-1.

7. **DEFENDANT'S WITNESSES**

A. **On liability, defendants intends to call the following witnesses who will testify in accordance with the following summaries:**

1. Steven Humphrey, Director, Biomechanics
Zimmer, Inc.
345 East Main Street
Warsaw, IN 46580

Mr. Humphrey has knowledge or information regarding the design, testing and manufacture of the NexGen system and the device at issue, as well as Zimmer's defenses with respect to any alleged product defect.

B. **On damages, Defendant intends to call the following witnesses who will testify in accordance with the following summaries:**

1. Alfred J. Tria, M.D., and his Custodian of Records
Orthopedic Center of New Jersey
1527 Route 27, Suite 1300
Somerset, NJ 08873

Dr. Tria will testify concerning Dr. Selinger's medical history, implant and explant of the Device, rehabilitation of Dr. Selinger's right knee, and future prognosis of the knee.

2. Frank F. Cook, M.D. , and his Custodian of Records
Palm Beach Orthopedic Institute
2055 Military Trail, Suite 200
Jupiter, FL 33458

Dr. Cook will testify concerning Dr. Selinger's medical history and treatment of his right knee.

3. Robert L. Diaz, M.D., and his Custodian of Records
Palm Beach Orthopedic Institute
2055 Military Trail, Suite 200
Jupiter, FL 33458

Dr. Diaz will testify concerning Dr. Selinger's medical history,

rehabilitation of Dr. Selinger's right knee, and future prognosis of the knee.

4. Mrs. Emilia Selinger (plaintiff)

5. Dr. Lawrence Selinger (plaintiff)

6. Custodian of Records
Saint Peter's University Hospital
254 Easton Avenue
New Brunswick, NJ 08901

Witness will authenticate records if necessary.

7. Custodian of Records
Orthopedic Center of New Jersey
1527 Route 27, Suite 1300
Somerset, NJ 08873

Witness will authenticate records if necessary.

8. Custodian of Records
Shore Rehabilitation Institute
6258 Jack Martin Blvd.
Brick, NJ 08723

Witness will authenticate records if necessary.

9. Custodian of Records
Advantage Physical Therapy
990 Cedarbridge Avenue, Unit B 16
Brick, NJ 08723

Witness will authenticate records if necessary.

10. Custodian of Records
Well Again Co.
639 Broadway
Long Branch, NJ 07740

Witness will authenticate records if necessary.

11. Custodian of Records
Palm Beach Orthopedic Institute
2055 Military Trail, Suite 200

Jupiter, FL 33458

Witness will authenticate records if necessary.

12. Custodian of Records
Eric W. Roberts, MSPT
600 Heritage Drive, Suite 110
Jupiter, FL 33458

Witness will authenticate records if necessary.

13. Custodian of Records
Body and Soul Wellness Center
784 US Highway 1
North Palm Beach, FL 33408

Witness will authenticate records if necessary.

8. **EXPERT WITNESSES**

A. Plaintiffs' expert witnesses are:

(1.) Alfred J. Tria, M.D.
Orthopedic Center of New Jersey
1527 Route 27, Suite 1300
Somerset, NJ 08873

B. Zimmer's objections to the qualifications of Plaintiffs' expert are:

Dr. Tria has no qualifications to opine in the following areas:

(a) Alleged Manufacturing defect
(b) Causation
(c) Bio-mechanical Engineering

See Zimmer Inc.'s Brief in Support of Its Motion *In Limine* to Exclude the Testimony of Plaintiffs' Expert Alfred J. Tria, Jr., M.D., Record Document 20-1.

C. Zimmer's expert witnesses are:

(1.) Charles Clark, M.D.
Department of Orthopaedic Surgery
01008 JPP
200 Hawkins Drive
Iowa City, IA 52242

(2.) Steven Kurtz, Ph.D.
Exponent
3401 Market Street, Suite 300
Philadelphia, PA 19104

The CVs of Zimmer's experts are attached at Tab "Exhibit A."

D. Plaintiffs' objections to the qualifications of Zimmer's experts are:

None.

9. PLAINTIFFS' EXHIBITS

1. NexGen knee as described above
2. Operative photos
3. Hospital chart including operative report relative to 2004 surgery
4. Hospital chart including operative report relative to 2006 surgery

10. DEFENDANT'S EXHIBITS

1. Package Insert: NexGen Cruciate Retaining (CR), Legacy Posterior Stabilized (LPS) and Constrained Condylar (LCCK); CR-Flex (Fixed and Mobile Bearing) and LPS-Flex (Fixed and Mobile Bearing)/LPS-Mobile and LCCK Mobile Bearing Knee, Lit No. 87-6203-883-00, Rev. C (ZIM/SEL 0001 – ZIM/SEL 0006)
2. Surgical Technique: Zimmer Legacy Knee LPS-Flex Fixed Bearing Knee Surgical Technique, Lit No. 97-5964-102-00 10ML (ZIM/SEL 0007 – ZIM/SEL 00017)
3. NexGen Product Brochure
4. Device History Records, including design prints.
5. Design Assurance File
6. 510(k)
7. MedWatch Report
8. Photographs or demonstrations of testing of NexGen components
9. Charles Clark, M.D.'s report
10. Charles Clark, M.D.'s curriculum vitae
11. References cited in Charles Clark, M.D.'s report
12. Steven Kurtz, Ph.D's report
13. Steven Kurtz, Ph.D's curriculum vitae
14. References cited in Steven Kurtz, Ph.D's report
15. Medical records from Saint Peter's University Hospital for care and treatment of Lawrence Selinger

16. Medical records from Orthopedic Center of New Jersey for care and treatment of Lawrence Selinger
17. Medical records from Shore Rehabilitation Institute for care and treatment of Lawrence Selinger
18. Medical records from Advantage Physical Therapy for care and treatment of Lawrence Selinger
19. Medical records from Well Again Co. for care and treatment of Lawrence Selinger
20. Medical records from Palm Beach Orthopedic Institute for care and treatment of Lawrence Selinger
21. Medical records from Eric W. Roberts, MSPT, Spine for care and treatment of Lawrence Selinger
22. Medical records from Wellness Center for care and treatment of Lawrence Selinger
23. Medical records from Upledger Institute Healthplex for care and treatment of Lawrence Selinger
24. Medical records from Community Medical Center for care and treatment of Lawrence Selinger
25. Medical records from JFK Johnson Rehabilitation Institute for care and treatment of Lawrence Selinger
26. Medical records from Alfred J. Tria, M.D. for care and treatment of Lawrence Selinger
27. Medical records from Lin Lei, M.D., for care and treatment of Lawrence Selinger
28. Medical records from Robert L. Diaz, M.D., for care and treatment of Lawrence Selinger
29. X-ray, MRI, or other demonstrative exhibit of normal knee
30. X-ray, MRI, or other demonstrative exhibit of lower extremities with parts labeled
31. X-rays, MRIs, or other illustrations of the lower extremities of Lawrence Selinger taken at Orthopedic Center of New Jersey
32. X-rays, MRIs, or other illustrations of the lower extremities of Lawrence Selinger taken at St. Peter's University Hospital
33. Animations of demonstration of knee implant, gait model, and knee motion
34. Demonstrative implant stress analysis models
35. Demonstrative proximal medial bone loss models
36. Demonstrative predictive stresses within femoral component models
37. Exemplar of NexGen Knee.
38. NexGen device explanted from Plaintiff Lawrence Selinger
39. Correspondence from Lawrence Selinger to Susan Wihibrink dated May 23, 2007
40. Pictures of Zimmer facilities
41. All documents produced by any party in this case

42. All pleadings filed in this case
43. All exhibits to any depositions taken in connection with this case
44. All discovery responses served by any party in this case
45. All exhibits necessary for impeachment or rebuttal
46. Demonstrative exhibits yet to be identified

11. PLAINTIFFS' LEGAL ISSUES

Whether or not defendant's product had a manufacturing defect that was the proximate cause of the need to explant it and replace it with another knee prosthesis.

12. DEFENDANT'S LEGAL ISSUES

A. This Case Falls Within the NJ Product Liability Act, and Plaintiffs' Proofs Will Be Inadequate to Support the Claims

The Product Liability Act makes clear that a product liability action is the sole remedy available to a plaintiff who claims to have been harmed by an allegedly defective product. N.J.S.A. § 2A:58C-1 *et seq.* This is the only avenue for recovery in this case. As set forth in detail below, insofar as there may be a legal basis for Plaintiffs' claims, they must establish: (1) that the product was defective; (2) that the alleged defect existed at the time that it was under the defendant's control; and (3) that the alleged defect was the proximate cause of Plaintiffs' injury. *Ebenhoech v. Koppers Ind., Inc.*, 239 F. Supp.2d, 455, 473 (D.N.J. 2002) (applying New Jersey law). Failure to prove any of these three elements must lead to a judgment against the plaintiff. *O'Brien v. Muskin Corp.*, 94 N.J. 175, 179-80 (1983).

Plaintiffs further allege that Zimmer's acts or omissions were done negligently and with wanton and willful disregard of the safety of foreseeable users such that Plaintiffs are entitled to punitive damages. Plaintiff Emilia Selinger also seeks relief for lack of consortium. Plaintiffs' also fail to meet their burden with respect to these two claims.

B. Plaintiffs' Manufacturing and Design Defect Claims Lack the Necessary Evidence Support

Plaintiffs have no evidence that the device implanted in Plaintiff Dr. Selinger was manufactured in a manner inconsistent with the specifications and design Zimmer submitted to the FDA in connection with its application to market the product. Likewise, Plaintiffs have no evidence to support a defective design claim. Indeed, Plaintiffs have failed to designate expert testimony in support of central elements of their claims, which is required to make a *prima facie* showing and survive summary judgment. *See, e.g., Lander v Teaneck Volunteer Ambulance Corps*, 368 N.J. Super. 320, 331 (App. Div. 2004). Moreover, Plaintiffs do not have admissible expert testimony required under New Jersey law to establish the material fact of whether the

Device contained a manufacturing or design defect or that Zimmer failed to establish proper warnings. *Sparrow v. La Cachet, Inc.*,305 N.J. Super. 301, 304 (App. Div. 1997).

C. General and Specific Causation Are Essential Elements of Plaintiffs' Claims, and Plaintiffs Cannot Establish These Issues

To sustain their claims against Zimmer, Plaintiffs must prove both product defect causation and medical causation. Plaintiffs must provide *prima facie* evidence that the product was defective, that the defect existed when the product left the Zimmer's control, and that the defect caused injury to a reasonably foreseeable user. More importantly, Plaintiffs must also prove to a reasonable degree of medical probability that the condition of the product was a substantial factor in bringing about the injury. Plaintiffs cannot meet these burdens.

D. The General and Specific Causation Elements of Plaintiffs' Claims Cannot Withstand Scrutiny Under F.R.E. 702

As reflected elsewhere in this Order, Zimmer maintains that central aspects of this case that rest upon opinion testimony of a single liability expert, including key issues with regard to causation, cannot withstand scrutiny under F.R.E. 702/*Daubert*. The Court, in its role as gatekeeper, should keep such dubious testimony out of this case.

E. Zimmer Complied with Applicable FDA Regulations

Zimmer complied with FDA regulations and guidelines. Simply put, the product at issue met all such requirements.

F. Compensatory Damages

Plaintiffs' claims for compensatory damages are speculative and not adequately supported by the proofs, expert or otherwise. This aspect of Plaintiffs' case should not go to the jury, even if Plaintiffs can reach a jury with respect to their design and warning claims against Zimmer.

G. Punitive Damages

Punitive damages are not available in medical device cases under the New Jersey Product Liability Act (see N.J. Stat. Ann. § 2A:58C-5 and the statutory exception allowing punitive damages where the defendant knowingly misled the FDA is preempted by federal law. *See McDarby v. Merck & Co.*, 401 N.J. Super. 10, 87-94 (App. Div. 2008); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that fraud-on-the-FDA claims were impliedly preempted by federal law).

Even if punitive damages were recognized, Plaintiffs' claims for punitive damages find no support in the record. In order to recover punitive damages, a plaintiff much prove, by clear and

convincing evidence, actual malice or a wanton and willful disregard for safety of persons who foreseeably might be harmed. Here, Plaintiffs have no evidence that Zimmer acted with actual malice or willful and wanton disregard for the safety of others. In fact, the evidence that Zimmer will present is to the contrary. Zimmer will show that it acted cautiously in all respects and that Zimmer is known in the industry as a conservative company that places patient safety as its highest priority.

H. Proof Issues

In addition to these legal issues, defendants have raised a number of legal issues to be addressed *in limine* (see ¶14).

13. CHOICE OF LAW

The parties agree that this case is governed by New Jersey law.

14. MISCELLANEOUS

Defendants intend to file at least the following motions *in limine* regarding evidentiary issues and Plaintiffs' experts.

(1) Motion *in limine* to exclude evidence of marketing motives, assets and profitability, executive compensation and liability insurance.

(2) Motion *in limine* to exclude lay opinions regarding economic loss.

(3) Motion *in limine* to exclude advertising and marketing materials not seen by Plaintiffs.

(4) Motion *in limine* to exclude references to other claims, lawsuits, or alleged failures, or to samples of products not used by Plaintiffs.

(5) Motion *in limine* to exclude duplicative and cumulative witness testimony.

(6) Motion *in limine* to preclude reference to the attendance at trial all times *vel non* of the Defendants' respective corporate representatives.

(7) Motion *in limine* to exclude reference to medical expenses that are not proven to be "reasonable and necessary".

(8) Defendants reserve the right to file additional motions *in limine* as appropriate in accordance with the schedule set by the Court.

15. **JURY TRIALS** - Not later than ten (10) days prior to trial

A. Each side shall submit to the Judge and to opposing counsel a trial brief or memorandum in accordance with Local Civil Rule 7.2B, with citations to authorities and arguments in support of its position on all disputed issues of law. In the event a brief shall not be filed, the delinquent party's complaint or defense may be stricken.

B. Counsel for each party shall submit to the Judge, with a copy to opposing counsel, written requests for instructions to the jury. Supplemental requests for instructions may be submitted at any time prior to argument to the jury. All requests for instructions shall be plainly marked with the name and number of the case, shall contain citations of supporting authorities, if any, and shall designate the party submitting same. In the case of multiple requests by a party, these shall be numbered in sequence and each request shall be on a separate sheet of paper.

C. Joint proposed verdict form/special interrogatories are to be submitted to the trial judge.

16. **NON-JURY TRIALS - NOT APPLICABLE**

17. **TRIAL COUNSEL**

Plaintiffs:

Dennis A. Drazin, Esq.
John R. Connelly Jr. , Esq.
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Defendant:

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Newark, New Jersey 07101-0652

18. **BIFURCATION**

The issue of liability and damages SHALL/**SHALL NOT** be tried separately.

19. **ESTIMATED LENGTH OF TRIAL**

Five to six days.

AMENDMENT TO THIS PRETRIAL ORDER WILL NOT BE PERMITTED UNLESS THE COURT DETERMINES THAT MANIFEST INJUSTICE WOULD RESULT IF THE AMENDMENT IS DISALLOWED.

/s John R. Connelly Jr., Esq.
(ATTORNEY FOR PLAINTIFFS)

/s Edward J. Fanning, Jr., Esq.
(ATTORNEY FOR DEFENDANT)

UNITED STATES MAGISTRATE JUDGE
DOUGLAS E. ARPERT

Dated: October 20, 2010